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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,333	08/20/2003	Bernd Disse	01-1196-1-C1	6665
28519 7590 03/11/2009 MICHAEL P. MORRIS BOEHRINGER INGELHEIM USA CORPORATION 900 RIDGEBURY RD P O BOX 368 RIDGEFIELD, CT 06877-0368				
EXAMINER				
SAMALA, JAGADISHWAR RAO				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
03/11/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/644,333

**Applicant(s)**

DISSE, BERND

**Examiner**

JAGADISHWAR R. SAMALA

**Art Unit**

1618

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/03/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9, 11-23 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 11-23 and 25-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of Applicant's Arguments/Remarks filed on 12/23/2008.

Claims 9, 11-23 and 25-32 are pending in the instant application.

### **Claim Rejections - 35 USC § 102**

1. Claims 9, 11-15, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Maesen et al (European Respri. J, 8, 1506-1513, 1995) **are maintained** for reasons of record in the previous office action filed on 08/05/2008.

### **Response to Arguments**

2. Applicant's arguments filed on 12/23/2008 have been fully considered but they are not persuasive. Applicant argues that Maesen reference teaches only a method for treating COPD and would not anticipate a method for treating cystic fibrosis, idiopathic lung fibrosis or fibrosing alveolitis and, an inflammatory component thereof. This argument is not persuasive because, inhalation of tiotropium bromide has a long bronchodilator activity in patients with COPD, given the broadest reason of interpretation, COPD is not one disease and is generally thought to be an umbrella term encompassing chronic (obstructive) bronchitis, emphysema (a chronic lung disease which affects the alveoli and/or the ends of smallest bronchi), small airway disease associated with inflammation, disordered repair of injured airway epithelium and loss of structural integrity. It is obvious that the treating COPD will overlap treating fibrosis ( see page s47 col.1 lines 51-57).The main histopathological changes in small airway disease

involve an appearance and increase in number of goblet cells, an increase in the amount of mucus in the lumen, the presence of inflammation, an increase in muscle mass in the walls of the bronchioles, and ultimately, fibrosis and obliteration, causing airway narrowing. And emphysematous lungs focal areas with fibrosis are observed, often owing to reactive changes associated with large bullae. The functional and structural narrowing of the conducting airways caused by bronchiolar impairment, due to acute or chronic airway changes such as bronchial wall edema and/or increased luminal secretions more evident in more advanced stages of COPD, would be at the origin of the increased dispersion of alveolar ventilation (see Am. J. Respir. Crit. Care Med., Vol 159, s41-s66, 1999 entire article). Therefore, taking into consideration the treatment of symptoms of COPD would inherently treat cystic fibrosis, emphysema or fibrosing alveolitis.

### **Claim Rejections - 35 USC § 103**

3. Claims 9, 11-23 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maesen et al (European Respir. J, 8, 1506-1513, 1995) as applied to claim 9, 11-15, 31 and 32 above, and further in view of Skupin (US 5,250,286) and Hochrainer et al (US 6,150,418) **are maintained** for reasons of record in the previous office action filed on 08/05/2008.

Applicant argues that Maesen teaches only a method for treating COPD and fails to teach or suggest a method for treating an inflammatory component of a disease selected from cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis and also

argues that there is no motivation to combine Skupin and Hochrainer reference. This argument is not persuasive because, Maesen reference meets the claim limitation as discussed above.

2. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Skupin reference is relied upon for treatment of symptoms of COPD, including cystic fibrosis, and emphysema by administering an alpha-adrenergic blocking agent to a patient by inhalation and Hochrainer reference is relied upon for administering a beta-stimulator drug in inhalation therapy of respiratory diseases comprising pharmaceutically suitable and therapeutically useful substance which is not an active substance but can be formulated together with the active drug in the pharmacologically suitable solvent or suspension agent in order to improve the qualitative properties of the active substance concentrate or the pharmaceutical preparation which is to be obtained by dilution ready for inhalation .

### **Conclusion**

1. No claims are allowed at this time.
3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala  
Examiner  
Art Unit 1618

sjr